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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,702

09/13/2006

Richard Martin

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MCDONNELL BOEHNEN HULBERT @ BERGHOFF LLP
300 SOUTH WACKER DRIVE
SUITE 3100
CHICAGO, IL 60606

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

09/30/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,702	Applicant(s) MARTIN ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 and 48 is/are pending in the application.
- 4a) Of the above claim(s) 6-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 32-42, 44, 46 and 48 is/are rejected.
- 7) ☒ Claim(s) 43 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-46 and 48 are pending in the application.

This action is in response to applicants' amendment filed July 14, 2010. Claims 1-3, 7, 23, 34, 42, 45, 46 and 48 have been amended and claim 47 has been canceled.

Response to Amendment

Applicant's amendments filed July 14, 2010 have been fully considered with the following effect:

1. The Applicants' traversal of claims 6-31 as being withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention is **herein moot**, the Election filed February 5, 2010 was treated as an election **without traverse** (MPEP § 818.03(a)).

The election of an **invention** i.e. Group I, or species may be made with or without traverse. **To preserve a right to petition, the election must be made with traverse.** If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. **Traversal must be presented at the time of election in order to be considered timely.** Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

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2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3) in the last office action, which is hereby **withdrawn**.

3. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections labeled paragraph 4) in the last office action, which is hereby **withdrawn**.

4. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejections labeled paragraph 5) in the last office action, which is hereby **withdrawn**.

5. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 6b), e), g), j), l), m), n) and u) in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 6a), c), d), f), h), i), k), o), p), q), r), s) and t) maintained in the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

a) The applicants' state that claim 1 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{33} and R^{34} . The Applicants respectfully disagree. The definition of R^{30} and R^{31} , which precedes the definition of R^{33} and R^{34} can independently be, for example, $-N(R^{33})R^{34}$, thereby providing antecedent basis for R^{33} and R^{34} . However, the rejection was not that there were no variable R^{33} and R^{34} but that they lack antecedent basis in

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the definition where (b) R^{33} and R^{34} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclyl ring, or an optionally substituted heteroaryl ring, and the others of R^{32} , R^{33} , R^{34} , R^{35} and R^{36} are selected as in (a) above. Since the R^{33} and R^{34} are taken together to form a ring they cannot be "selected as in (a) above".

Claims 1-5, 32, 33 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

c) The applicants' state that claim 1 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{15} and R^{16} . The Applicants respectfully disagree. R^{15} and R^{16} appear for the first time in moieties within the definitions of R^1 and R^2 and are then defined later in the claim, so the applicants respectfully submit that there is no antecedent basis problem with R^{15} and R^{16} . However, the rejection was not that there were no variable R^{15} and R^{16} but that they lack antecedent basis in the definition where (b) R^{15} and R^{16} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclyl ring, or an optionally substituted heteroaryl ring, and the others of R^{14} , R^{15} , R^{16} , R^{17} and R^{18} are selected as in (a) above. Since the R^{15} and R^{16} are taken together to form a ring they cannot be "selected as in (a) above".

Claims 1-5, 32, 33 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

d) The applicants' state that claim 1 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{21} and R^{22} . The Applicants respectfully disagree. R^{21} and R^{22} appear for the first time in moieties within the definitions of R^4 , R^5 , R^6 and R^7 and are then defined later in the claim, so the applicants respectfully submit that there is no antecedent basis problem with R^{21} and R^{22} . However, the rejection was not that there were no variable R^{21} and R^{22} but that they lack antecedent basis in the definition where (b) R^{21} and R^{22} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclyl ring, or an optionally substituted heteroaryl ring, and the others of R^{20} , R^{21} , R^{22} and R^{24} are selected as in (a) above. Since the R^{21} and R^{22} are taken together to form a ring they cannot be "selected as in (a) above".

Claims 1-5, 32, 33 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

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f) The applicants' state that the recitation of a counterion is not necessary to define the applicants' invention nor for one of ordinary skill in the art to understand the meaning of the claim and its scope. However, there is no counterion indicated and a "compound" is not an ion.

Claims 1-5, 32, 33 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

h) The applicants' state that claim 34 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{15} and R^{16} . The Applicants respectfully disagree. R^{15} and R^{16} appear for the first time in moieties within the definitions of R^1 and R^2 and are then defined later in the claim, so the applicants respectfully submit that there is no antecedent basis problem with R^{15} and R^{16} . However, the rejection was not that there were no variable R^{15} and R^{16} but that they lack antecedent basis in the definition where (b) R^{15} and R^{16} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclyl ring, or an optionally substituted heteroaryl ring, and the others of R^{14} , R^{15} , R^{16} , R^{17} and R^{18} are selected as in (a) above. Since the R^{15} and R^{16} are taken together to form a ring they cannot be "selected as in (a) above".

Claims 34-42, 44 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

i) The applicants' state that claim 34 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{21} and R^{22} . The Applicants respectfully disagree. R^{21} and R^{22} appear for the first time in moieties within the definitions of R^4 , R^5 , R^6 and R^7 and are then defined later in the claim, so the applicants respectfully submit that there is no antecedent basis problem with R^{21} and R^{22} . However, the rejection was not that there were no variable R^{21} and R^{22} but that they lack antecedent basis in the definition where (b) R^{21} and R^{22} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclcyl ring, or an optionally substituted heteroaryl ring, and the others of R^{20} , R^{21} , R^{22} and R^{24} are selected as in (a) above. Since the R^{21} and R^{22} are taken together to form a ring they cannot be "selected as in (a) above".

Claims 34-42, 44 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

k) The applicants' state that the recitation of a counterion is not necessary to define the applicants' invention nor for one of ordinary skill in the art to

understand the meaning of the claim and its scope. However, there is no counterion indicated and a “compound” is not an ion.

Claims 34-42, 44 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

o) The applicants' state that claim 46 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{33} and R^{34} . The Applicants respectfully disagree. The definition of R^{30} and R^{31} , which precedes the definition of R^{33} and R^{34} can independently be, for example, $-N(R^{33})R^{34}$, thereby providing antecedent basis for R^{33} and R^{34} . However, the rejection was not that there were no variable R^{33} and R^{34} but that they lack antecedent basis in the definition where (b) R^{33} and R^{34} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclyl ring, or an optionally substituted heteroaryl ring, and the others of R^{32} , R^{33} , R^{34} , R^{35} and R^{36} are selected as in (a) above. Since the R^{33} and R^{34} are taken together to form a ring they cannot be “selected as in (a) above”.

Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

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p) The applicants' state that, claim 46 was rejected for the recitation of a period at the end of the definition of R^4 , R^5 , R^6 , and R^7 . The claims have herein been amended to replace the period with semicolon. However, the period still appears in claim 46.

Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

q) The applicants' state that claim 46 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{15} and R^{16} . The Applicants respectfully disagree. R^{15} and R^{16} appear for the first time in moieties within the definitions of R^1 and R^2 and are then defined later in the claim, so the applicants respectfully submit that there is no antecedent basis problem with R^{15} and R^{16} . However, the rejection was not that there were no variable R^{15} and R^{16} but that they lack antecedent basis in the definition where (b) R^{15} and R^{16} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclyl ring, or an optionally substituted heteroaryl ring, and the others of R^{14} , R^{15} , R^{16} , R^{17} and R^{18} are selected as in (a) above. Since the R^{15} and R^{16} are taken together to form a ring they cannot be "selected as in (a) above".

Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention, for reasons of record and stated above.

r) The applicants' state that claim 46 and those dependent thereon were rejected for lack of antecedent basis for the recitation of R^{21} and R^{22} . The Applicants respectfully disagree. R^{21} and R^{22} appear for the first time in moieties within the definitions of R^4 , R^5 , R^6 and R^7 and are then defined later in the claim, so the applicants respectfully submit that there is no antecedent basis problem with R^{21} and R^{22} . However, the rejection was not that there were no variable R^{21} and R^{22} but that they lack antecedent basis in the definition where (b) R^{21} and R^{22} , together with the nitrogen atom to which they are attached, form an optionally substituted heterocyclyl ring, or an optionally substituted heteroaryl ring, and the others of R^{20} , R^{21} , R^{22} and R^{24} are selected as in (a) above. Since the R^{21} and R^{22} are taken together to form a ring they cannot be "selected as in (a) above".

Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

s) The applicants' state that while the applicants respectfully traverse, they have amended the claims to recited each of R^1 through R^{24} and R^{30} through R^{36} , thereby obviating this rejection. However, this is not so in claim 46.

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Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

t) The applicants' state that the recitation of a counterion is not necessary to define the applicants' invention nor for one of ordinary skill in the art to understand the meaning of the claim and its scope. However, there is no counterion indicated and a "compound" is not an ion.

Claims 46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated July 14, 2010, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34-42, 44 and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutically acceptable salt thereof, does not reasonably provide enablement for esters, enol ethers, enol esters,

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acetals, ketals, orthoesters, hemiacetals, hemiketals, acids and bases thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claim is drawn to esters, enol ethers, enol esters, acetals, ketals, orthoesters, hemiacetals, hemiketals, acids and bases. But the numerous examples presented all failed to produce an esters, enol ethers, enol esters, acetals, ketals, orthoesters, hemiacetals, hemiketals, acids or bases. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 “The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist.” Hence, applicants must show that esters, enol ethers, enol esters, acetals, ketals, orthoesters, hemiacetals, hemiketals, acids and bases can be made, or limit the claims accordingly.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-5, 32-42, 44 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R^8 in the 7th line of page 5. There is no variable R^8 in the claim.
- b. Claim 34 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of R^8 in the 23rd line of page 18. There is no variable R^8 in the claim.
- c. Claim 42 is vague and indefinite in that it is not known what is meant by the period which appears at the end of the definition of R^6 and R^7 .

Claim Objections

8. Claim 42 is objected to because of the following informalities: the moiety - $C(O)NCH(CH_3)(CH_2CH_3)$ in the definition of R^1 appears to be missing a valency on the nitrogen atom. Appropriate correction is required.
9. Claims 43 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. This application contains non-elected subject matter in claims 1, 32, 33, 34, 46 and claims dependent thereon are drawn to an invention nonelected without traverse in the reply filed on February 5, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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11. This application contains claims 6-31 drawn to an invention nonelected without traverse in the reply filed on February 5, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624